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INTERNATIONAL COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 489081 BMP	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/NZ2003/000243	International Filing Date (day/month/year) 29 October 2003	Priority Date (day/month/year) 12 November 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. 7 A61 M 16/16		
Applicant FISHER & Paykel Healthcare Limited (et al.)		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand <b>05 APR 2004</b>	Date of completion of the report 21 February 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>MATTHEW FORWARD</b> Telephone No. (02) 6283 2606

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/NZ2003/000243

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

 the international application as originally filed. the description, pages , as originally filed,

pages , filed with the demand,

pages , received on with the letter of

 the claims, pages , as originally filed,

pages , as amended (together with any statement) under Article 19,

pages , filed with the demand,

pages , received on with the letter of

 the drawings, pages , as originally filed,

pages , filed with the demand,

pages , received on with the letter of

 the sequence listing part of the description:

pages , as originally filed

pages , filed with the demand

pages , received on with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished4.  The amendments have resulted in the cancellation of: the description, pages the claims, Nos. the drawings, sheets/fig.5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	YES
	Claims 1-18	NO
Inventive step (IS)	Claims	YES
	Claims 1-18	NO
Industrial applicability (IA)	Claims 1-18	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 JP 9-276408

D2 DE 19630466

D3 WO 2001/010489

The present claims define a breathing assistance apparatus comprising a gas delivery device adapted to provide gas at a substantially positive mean pressure; a humidifier adapted to humidify said gas and; wherein said apparatus is configurable to at least two configurations, a first configuration with a predetermined functionality inoperable with said gas delivery device operable and a second configuration with said predetermined functionality and said device operable.

**NOVELTY (N): Claim 1 to 18**

Document D1 discloses a breathing apparatus with positive pressure as piping means are provided. Humidification means (14) are provided to humidify the first stream of oxygen which is mixed with the second stream of oxygen which is dry. The humidification degree of the combined stream of two original streams of oxygen is changed by adjusting the flow of humidified oxygen (first stream) by controlling the orifice. As a result the disclosed apparatus is configurable to at least two configurations, a first configuration with a predetermined functionality inoperable with said gas delivery device inoperable (when orifice is closed and first stream of humidified oxygen is not mixing with second stream of dry oxygen) and a second configuration with said predetermined functionality and said device operable (when orifice is opened and first stream of humidified oxygen is mixing with second stream of dry oxygen) (abstract, Fig. 1-4). Claims 1-18 are not new in view of this citation.

Document D2 discloses a device for gas supply for sleep apnea with a respiratory gas source. The flow guiding element (3) of the device has at least two pre-selectable delivery paths (6a, 6b), a first flow path (6a) leading to the respiratory opening of the patient, bypassing the gas humidifier (5), and a second flow path (6b) leading to the respiratory opening of the patient via an admixing area (7). This admixing area (7) is connected with the gas humidifier (5). The valve system (10) could be used to control the delivery of the gas. As a result the disclosed device is configurable to at least two configurations, a first configuration with a predetermined functionality inoperable with said gas delivery device inoperable and a second configuration with said predetermined functionality and said device operable (abstract, Fig. 1-4). Claims 1-18 are not new in view of this citation.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of V**

Document D3 discloses a device for supplying a respiratory gas having a humidifying device, a respiratory gas tube, and a connecting device therefore. The humidifying device is characterized by the provision of a partial quantity delivery device for delivering a partial quantity of the liquid pre-stored in a liquid storage space into humidifying area. As a result the disclosed apparatus is configurable to at least two configurations, a first configuration with a predetermined functionality inoperable with said gas delivery device operable and a second configuration with said predetermined functionality and said device operable (abstract, Fig. 1-6). Claims 1-18 are not new in view of this citation.

Documents D1 to D3 are considered to disclose all the features of claims 1 to 18. Consequently these claims lack an inventive step.